

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

v.

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8422

Bartle, C.J.

March 10, 2010

Edward Huntington ("Mr. Huntington" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement §§ IV.B.1.a. & I.22.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Dean G.

2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

Karalis, M.D. Based on an echocardiogram dated October 10, 2002, Dr. Karalis attested in Part II of Mr. Huntington's Green Form that claimant suffered from mild aortic regurgitation, aortic stenosis,³ and had surgery to repair or replace his aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.⁴ Based on such findings, claimant would be entitled to Matrix B-1, Level III benefits in the amount of \$129,832.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Jeffrey Williams, M.D., stated that claimant had "Aortic Insufficiency - 1+/4+ regurgitation" Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is equal to or greater than 10% of the left

3. A finding of aortic stenosis requires the payment of reduced Matrix Benefits for aortic valve claims. See Settlement Agreement § IV.B.2.d.(2)(c)(i)e).

4. Dr. Karalis also attested that claimant suffered from mitral annular calcification, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits if he or she had "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Mr. Huntington underwent surgery to repair or replace the aortic valve following the use of Pondimin® and/or Redux™, the only issue is whether claimant is eligible for benefits.

ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In September, 2003, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding of mild aortic regurgitation because claimant's echocardiogram demonstrated only trace to no aortic regurgitation. Specifically, Dr. Oliner explained that "[aortic regurgitation] is not seen on parasternal long axis view, but is trace on apical 3 and apical 5 chamber views, with a very narrow jet."

Based on the auditing cardiologist's finding of trace to no aortic regurgitation, the Trust issued a post-audit determination denying Mr. Huntington's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a verified supplemental opinion from Dr. Karalis, who stated that "the apical 3 and apical 5 chamber views ... show mild, not trace or trivial regurgitation." Dr. Karalis measured claimant's JH/LVOTH as "approximately 15%." Claimant also included a verified opinion from Dr. Williams, who

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Huntington's claim.

concurred with Dr. Karalis that Mr. Huntington had mild aortic regurgitation. Additionally, claimant submitted a verified opinion from Shelley Shapiro, M.D., who measured claimant's JH/LVOTH as approximately 14% and, like Dr. Karalis, based her finding on the apical 3 and apical 5 chamber views. Dr. Shapiro further stated that "aortic insufficiency is not seen on the parasternal long axis view [because] of imaging technique and quality and not to an absence of the abnormality." Claimant argued that the detailed findings of these three cardiologists provided a reasonable medical basis for his claim. Claimant also argued that the auditing cardiologist failed to quantify his level of aortic regurgitation.

In response, the Trust submitted Mr. Huntington's claim to Dr. Oliner for a second review. Based on this review, Dr. Oliner confirmed his previous conclusion that there was no reasonable medical basis for the attesting physician's finding that Mr. Huntington had mild aortic regurgitation. In his supplemental declaration, Dr. Oliner stated, in relevant part, that:

I again concluded that Claimant's level of aortic regurgitation prior to his aortic valve replacement surgery was trace in real time.

In connection with my review, I evaluated Claimant's jet height and left ventricular outflow tract height in the frames relied upon by Claimant's Attesting Cardiologist and expert. I found that Claimant's aortic regurgitant jet was trivial, short in length and narrow in height. I again concluded that

the jet height was less than 10% of the left ventricular outflow height.

The Trust then issued a final post-audit determination, again denying Mr. Huntington's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Huntington's claim should be paid. On June 16, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3618 (June 16, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 16, 2004. Claimant submitted a sur-reply on September 1, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge—helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding of mild aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Huntington argues that a claimant has a diminished burden of proof because the typical standards of "more like[ly] than not" and "reasonable degree of medical certainty" are absent from the reasonable medical basis standard under the Audit Rules. Claimant asserts that he has met this diminished burden of proof by submitting the detailed findings of three cardiologists, all of whom found that claimant had mild aortic regurgitation. Claimant also notes that

Dr. Oliner did not quantify claimant's level of aortic regurgitation.

In response, the Trust argues that "the standard of review for the audit of a claim is whether there is a reasonable medical basis to support the representations of the Attesting Cardiologist, not whether one party can collect more opinions than the other." The Trust also asserts that, under the Settlement Agreement, aortic regurgitation is to be determined in the apical long-axis view only if the parasternal long-axis view is unavailable. The Trust contends that, because the parasternal long-axis view was available, claimant's physicians improperly based their findings on the apical view. Finally, the Trust disagrees with claimant's definition of the reasonable medical basis standard.

In his sur-reply, claimant asserts that his attesting physician and supplemental experts properly relied upon the apical view in finding mild aortic regurgitation because the parasternal view was "not available because of ... poor quality."⁸

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no

8. Claimant also asserts in his sur-reply that the Trust's argument regarding the attesting physician's reliance on the apical long-axis view was improperly asserted for the first time in the Trust's reply. We disagree. The Audit Rules limit the Trust to the issues raised by the claimant in his or her response and to the issues and evidence identified by the Trust in its Final Post-Audit Determination. See Audit Rule 28.

reasonable medical basis for finding mild aortic regurgitation.

In particular, Dr. Vigilante stated that:

[T]he parasternal long axis view was available and of good quality. Color flow imaging in the view failed to demonstrate aortic regurgitation. The apical 3 chamber and 5 chamber views were reviewed, also. Only trace aortic regurgitation was noted with the JH/LVOTH clearly less than 10%. The JH/LVOTH measured 8% in these views. Even allowing for inter-reader variability, this could not be read as mild. At no time in this echocardiogram was mild aortic regurgitation suggested in the apical views. Once again, no aortic regurgitation was seen in the parasternal long axis view.

After reviewing the entire Show Cause Record, we find that claimant is not eligible to receive Level III Matrix Benefits. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits for "[s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). Under this definition, claimant, if he were found to be eligible, would have met the requirements of a Level III claim as the Trust does not contest that he had surgery to replace his aortic valve following the use of Pondimin® and/or Redux™.

Claimant, however, must first establish his eligibility for benefits. In PTO No. 3192 (Jan. 7, 2004), we noted that simply meeting the definition of Matrix Level III as set forth in the Settlement Agreement is insufficient to qualify for Matrix Benefits. Rather, a claimant also must satisfy the eligibility

requirements set forth in Section IV.B.1.a. of the Settlement Agreement. See PTO No. 3192 at 3 ("Experiencing left sided valvular heart disease is of no moment unless the claimant also passes muster under § IV.B.1.a.").

The Settlement Agreement states that the following Class Members are eligible to receive Matrix Compensation Benefits:

Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement defines FDA Positive, in pertinent part, as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must establish at least mild aortic regurgitation to be eligible to seek Matrix Benefits for his Level III aortic valve claim.

Mr. Huntington does not establish that there is a reasonable medical basis for his attesting physician's finding that claimant suffers from mild aortic regurgitation. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Vigilante.⁹ Claimant does not challenge

9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Dr. Vigilante's conclusion that he had only trace aortic regurgitation in the apical views and no aortic regurgitation in the parasternal long-axis view. On this basis alone, claimant has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

We also disagree with claimant that the "reasonable medical basis standard" under the Audit Rules and Settlement Agreement is a diminished standard that can be met by presenting the opinions of three cardiologists who opine that Mr. Huntington had mild aortic regurgitation. We previously have interpreted the reasonable medical basis standard more stringently than claimant contends, and as one that must be applied on a case-by-case basis. See PTO No. 6339 at 11-12 (May 25, 2006). Here, both the auditing cardiologist and the Technical Advisor found that the parasternal long-axis view was available and that it did not demonstrate mild aortic regurgitation. The Settlement Agreement requires the level of aortic regurgitation to be determined in the parasternal long-axis view, and only in the apical long-axis view if the parasternal long-axis view is unavailable. See Settlement Agreement § I.22. In any event, both the auditing cardiologist and the Technical Advisor found that claimant had only trace to no aortic regurgitation in the apical views, which also precludes claimant from establishing a reasonable medical basis for his claim.

Finally, we disagree with Mr. Huntington's argument concerning the required method for evaluating a claimant's level

of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having mild aortic regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002) (examining appropriate standards for evaluating a patient's level of mitral regurgitation). The same principle applies to the evaluation of aortic regurgitation. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of aortic regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously evaluated and accepted in PTO No. 2640.¹⁰

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he had mild aortic regurgitation. Therefore, we will affirm the Trust's denial of Mr. Huntington's claim for Matrix Benefits.

10. Claimant's argument also fails because the Technical Advisor, although not required to, made a specific measurement of claimant's level of aortic regurgitation, which further establishes that claimant is not entitled to Matrix Benefits.